

Attorney Docket Number 2000.611 US PD

Remarks

The Examiner has objected to the specification for improper use of Trademarks. It is believed that all Trademarks with the exception of TITERMAX® found on page 23 were properly used. TITERMAX® has now been capitalized in accordance with the requirements. For this purpose only, a substitute page 23 is submitted herewith.

New claim 27 replaces claim 1, new claims 28, 29 and 30 replace claim 2, and new claim 31 replaces claim 22.

Claim 2 has been objected to for reciting material drawn to non-elected inventions. Claim 2 is now replaced with new claims 27, 28 and 29, which are all directed to whole cell vaccines.

Claim 22 stands rejected under 35 USC 112, first paragraph for lack of enablement.

Claim 22 has now been replaced with claim 31 directed to a method for protecting swine.

Claims 1-7, 22 and 26 stand rejected under 35 USC 112, second paragraph, for being indefinite. The Examiner has objected in claims 1 and 26 to the use of the phrase "antigens selected from the group consisting of 21 kDa, 31 kDa, 41 kDa..." The Examiner has asked whether applicant is listing molecular weights of antigens or merely naming the antigens.

Claim 27, replacing claim 1, now recites that the antigen is "selected from the group consisting of *L. intracellularis* antigens having the molecular weights of 21 kDa, 31 kDa, 41 kDa...". It is clear that these are the molecular weights of the antigens of *L. intracellularis*.

Attorney Docket Number 2000.611 US PD

Claims 1 and 26 are allegedly vague and indefinite for using the phrase "producing antibodies". Claim 27, replacing claim 1, now recites that the vaccine "induces an immune response resulting in the production of antibodies in a swine to which it has been administered..." Accordingly, it is believed that this objection is overcome.

Claims 6 and 7 are objected to for reciting trademarks.

Claims 6 and 7 have now been canceled with the present amendment.

Claims 1, 2 and 26 stand rejected under 35 USC 102 (b) for being anticipated by Joens et al, USP 5,610,059. Joens et al has been relied on for teaching methods of propagating *L. intracellularis*. The Examiner has commented that while Joens et al does not specifically disclose that the vaccine composition would induce the production of antibodies that specifically bind the recited antigen fragments, the ability to produce such antibodies would be an inherent property of the vaccine composition and that the recitation of "vaccine" in the present claims is intended use and does not distinguish over the composition of Joens et al.

The rejection over Joens et al is respectfully traversed. In Applicant's first patent, the biologically pure culture of the organism now referred to as *L. intracellularis* is described and claimed. In describing experimental work, Joens et al showed infection of pigs with the organisms produced in tissue culture, but they did not disclose experimental results showing protection or even the production of antibodies. All references to the production of antibodies, the determination of antigens and

Attorney Docket Number 2000.611 US PD

the making and use of a vaccine are prospective. There is no support for the vaccines or method presently claimed. All references to these subjects use the hypothetical "maybe," "could then," "could be," "may be," and etc. Only the isolated agent and its infectivity find support in the disclosure of the '059 patent.

Having shown that the disease agent has been isolated, it is predicted that "several envisioned strategies are now made practical which formerly would have been impossible." "...it is now possible to develop a bacterin, or inactivated preparation of the PPE-causing agent, using techniques known in the art, which may be administered to pigs at such time during immunological development as to permit the pigs to mount an effective immune response against the agent and against other PPE-causing agents that fall within the scope of the present invention. Bacterins are typically prepared by heat or chemical inactivation of an agent such a manner as to render the agent biologically ineffective yet antigenically intact." (Column 4 lines 4-16).

All of the description found in Joens et al, however, is merely predictive. As the Examiner has stated, "[w]hile the skill in the art of immunology is high, to date, prediction of protective immunity for any given composition is quite unpredictable." One can easily identify diseases for which years of effort have yet to yield effective vaccines. It cannot be said that Joens et al '059 has provided an enabling disclosure for a vaccine or its use. At most, it makes general reference to methods that one would use in an attempt to prepare vaccines relying solely on the knowledge in the art for details. At most, its suggestions make it obvious to try to make a vaccine.

Attorney Docket Number 2000.611 US PD

Claims 1-4, 22 and 26 stand rejected under 35 USC 102
(b) for anticipation or, alternatively, under 35 USC 103
(a) for obviousness over Joens et al '059.

The rejection of claims 1-4, 22 and 26 over Joens et al is respectfully traversed for the reasons set forth above. The '059 patent does not provide an enabling disclosure for a vaccine or a method of using it.

Claims 1-7, 22 and 26 stand rejected under 35 USC 103
(a) for being obvious over Joens et al '059.

Again, the rejection over Joens et al for obviousness is traversed. The fact that it is said that "the *L. intracellularis* culture could be used to develop a 'Bacterin' using techniques known in the art..." (emphasis added) does not provide an enabling disclosure as required under 35 USC 112, first paragraph. There is nothing to support a reasonable expectation of success in preparing an effective vaccine. In the words of the Examiner, "...prediction of protective immunity for any given composition is quite unpredictable." Moreover, there is nothing to suggest the specific antigens to which antibodies are raised in an immune response to the claimed vaccine, which are recited in independent claim 27.

In view of the above, it is believed that claims 3-5 and 27-31 are in condition for allowance. Favorable action is solicited.

Aug 05 02 03:09p

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p. 13

Aug 05 02 02:09p
Aug 05 02 12:52p

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p.1

Attorney Docket Number 2000.611 US PD

Should the Examiner consider that a conference would be helpful in advancing the prosecution of this application, he is invited to telephone applicant's attorney at the number below.

Respectfully Submitted,


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Attorney Docket Number 2000.611 US PD

Version with Markings to show changes made

3. The proliferative ileitis vaccine according to
[Claim 1] claim 27 further comprising an inactivating
agent [and an adjuvant].

Claims 27-31 have been added.